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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,943	01/29/2004	Yasuyuki Numajiri	00862.023438.	1830

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EXAMINER	
SHAW, AMANDA MARIE	
ART UNIT	**PAPER NUMBER**
1634	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/765,943	NUMAJIRI, YASUYUKI	
	Examiner	Art Unit	
	Amanda M. Shaw	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 17-26* is/are pending in the application.

4a) Of the above claim(s) *1-5,10-14 and 20-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-9, 15, 17-19, and 25-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 15, 2007 has been entered.

Claims 1-15 and 17-26 are currently pending. Claims 1-5, 10-14, and 20-24 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Claims 6, 15, 19, 25, and 26 have been amended. Therefore Claims 6-9, 15, 17-19, and 25-26 will be addressed herein.

Claim Objections

2. Claim 6 is objected to because the claim states, "reading a hybridization pattern in a DNA microarray". Hybridization patterns are read on DNA microarrays not in them. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6-9, 15, 17-19, and 25-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6-9 and 26 are indefinite because the claims do not recite an active process step of acquiring a first identification code in a positive, active fashion (see Ex parte Erlich 3USPQ2d, 101 1 (BPAI 1986)). Since the claims do not recite an active process step of acquiring a first identification code, it is unclear as to how analyzing a pattern obtained from the first DNA probe group is used to acquire a first identification code that identifies the subject. Further the claims do not recite an active process step of generating test information in a positive, active fashion (see Ex parte Erlich 3USPQ2d, 101 1 (BPAI 1986)). Since the claims do not recite an active process step of generating test information, it is unclear as to how analyzing a pattern obtained from the second DNA probe group is used to generate test information.

Claims 6-9 and 26 are indefinite over the recitation of the phrase "determining whether or not the subject is a new subject by comparing the first personal identification code obtained in the identification step with a second personal identification code registered in a database". This phrase in considered indefinite because it is unclear how one would determine if a subject is new by comparing the subject's personal identification code to only a single code in the registered database. Its seems like in order to determine if a subject is new, one would have to compare the subjects personal identification code to all of the codes in the registered database.

Claims 6-9 and 26 are indefinite over the recitation of the phrase "the hybridization pattern read" in claim 6. There is insufficient antecedent basis for this limitation in the claim because although the claim previously refers to a "reading a hybridization pattern" the claim does not refer to a "hybridization pattern read". Additionally the claims are indefinite over the recitation of the phrase "the first personal identification code" in claim 6. There is insufficient antecedent basis for this limitation in the claim because although the claim previously refers to a "first identification code" the claim does not refer to a "first personal identification code".

Claim 7 is indefinite because the claims do not recite any active process steps of the claimed method in a positive, active fashion (see Ex parte Erlich 3USPQ2d, 101 1 (BPAI 1986)). Since the claims do not recite any active process steps it is unclear how this claim further limits the method of claim 6.

Claim 7 is indefinite over the recitation of the phrase "a storage unit configured to store the subject". This phrase in considered indefinite because it is unclear if the storage unit is literally intended to store the body of the subject or if the identification information of the subject is stored.

Claim 8 is indefinite because the claims do not recite an active process step of analyzing the hybridization pattern of the first DNA probe group based on the structure of the first DNA probe group recognized based on the first identification indicator in a positive, active fashion (see Ex parte Erlich 3USPQ2d, 101 1 (BPAI 1986)). Since the claims do not recite an active process steps it is unclear how claim 8 further limits the identification step of claim 6.

Claim 8 is indefinite over the recitation of the phrase "the hybridization pattern of the first DNA probe group read" in claim 8. There is insufficient antecedent basis for this limitation in the claim because although the claim previously refers to a "reading a hybridization pattern on a DNA microarray containing a first DNA probe group" the claim does not refer to a "hybridization pattern of the first DNA probe group read".

Claim 9 is indefinite because the claims do not recite an active process step of analyzing the hybridization pattern of the second DNA probe group based on the structure of the second DNA probe group recognized based on the second identification indicator in a positive, active fashion (see Ex parte Erlich 3USPQ2d, 101 1 (BPAI 1986)). Since the claims do not recite an active process step it is unclear how claim 9 further limits the generation step of claim 6.

Claim 9 is indefinite over the recitation of the phrase "the hybridization pattern of the second DNA probe group read" in claim 9. There is insufficient antecedent basis for this limitation in the claim because although the claim previously refers to a "reading a hybridization pattern on a DNA microarray containing a second DNA probe group" the claim does not refer to a "hybridization pattern of the second DNA probe group read".

Claims 15, 17-19 and 25 are indefinite because the claims do not recite an active process step of generating test information in a positive, active fashion (see Ex parte Erlich 3USPQ2d, 101 1 (BPAI 1986)). Since the claims do not recite an active process step of generating test information, it is unclear as to how analyzing a pattern obtained from the second DNA probe group is used to generate test information. Further the claims do not recite an active process step of acquiring a first identification number for

the subject in a positive, active fashion (see Ex parte Erlich 3USPQ2d, 101 1 (BPAI 1986)). Since the claims do not recite an active process step of acquiring a first identification number, it is unclear as to how analyzing a pattern obtained from the first DNA probe group is used to acquire a first identification number.

Claims 15, 17-19 and 25 are indefinite over the recitation of the phrase "the hybridization pattern read" in claim 8. There is insufficient antecedent basis for this limitation in the claim because although the claim previously refers to a "reading a hybridization pattern" the claim does not refer to a "hybridization pattern read".

Claim 26 is indefinite over the recitation of the phrase "wherein the DNA microarray include a code for identifying itself, and the method further comprises a step of identifying a type of DNA microarray using the code". This phrase in considered indefinite because it is unclear how the code identifies for the microarray. For example it could mean that the code is used to identify the test being performed on the subject such that microarrays used to detect one disease such as (i.e. HIV) have one code and microarrays used to detect another disease (i.e. HPV) have a different code. Or it could mean that the code is used to identify the type of microarray such that microarrays comprising cDNAs would have one code and microarrays comprising RNAs would have another code.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6, 7, 15, 18, and 25 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Beecham (US Patent 5876926 Issued 1999) in view of Staub (US Patent 6187540 Issued 2001) and Wohlgemuth (US Patent 6905827 Filed 2002).

Regarding Claim 6 Beecham teaches a method comprising collecting a sample from a test subject and taking biometric data from the test subject. The biometric data permit a high order of probability of correlation of the test subject with the sample and with test results derived from the sample (Column 7 lines 5-10). Beecham teaches that the biometric data is used to determine the identity of the subject and that gene sequences can be used to uniquely identify a particular individual with a high degree of confidence in the accuracy of the identification (Column 10 lines 58-64). Beecham then teaches that the sample can be screened for an infectious disease such as HIV or for a genetic marker such as BRCA1 (Column 4-5). Beecham also teaches the method further includes a step of providing the test subject with a unique alphanumeric correlating code for permitting unique correlation of the test subject with the sample and with test results derived from the sample. The correlation code, biometric data, and the test result are linked as a single record in a database (Column 7 lines 10-15 and 62-64). Therefore one would be able to determine if a subject was new or not by searching the database for the unique alphanumeric correlation code.

Beecham et al do not teach a method which utilizes a DNA microarray to determine the identity of a subject and to test a sample for a disease or genetic condition.

However Staub teach that DNA microarrays can be used to determine the identity of newborn babies. Specifically Staub et al teach that the arrays can comprise thousands of oligonucleotide probes. Sample nucleic acid is allowed to hybridize with the probes and the hybridization conditions can be varied so that sample nucleic acid will only hybridize to a given probe if a perfect match is found. The hybridization pattern is then read and the identity of the subject can be determined (Column 7).

Additionally Wohlgemuth et al teach that cDNA microarrays can be used to detect the expression level on one or more genes and thereby enable one to diagnose or monitor disease (Abstract). Wohlgemuth also teach that DNA microarrays can have several subsets of probes which can be used for different purposes. Specifically Wohlgemuth et al teach that a diagnostic nucleotide set identified as a subset of sequences on a cDNA microarray can be utilized for diagnostic (or prognostic, or monitoring, etc.) purposes on the same array from which they were identified (column 48).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Beecham et al so as to have analyzed the biometric data using a DNA microarray comprising a set of probes which can be used to determine the identity of a subject and a set of probes which can

be used to test the sample for a disease or genetic condition in order to have achieved the benefits of using a method which allows for a powerful means of analyzing genetic information which utilizes automated scoring techniques and sophisticated data analysis software for collecting large amounts of data very quickly. Additionally having both probe sets on one microarray permits a high order of probability of correlation of the test subject with the sample and the test results derived from the sample.

Regarding Claim 7 Beecham et al teach a method wherein the unique alphanumeric correlation code, biometric indicia and the test results are stored as a single record in a database (Column 7).

Regarding Claim 15 Beecham et al teach a method for retrieving medical data from a database. The method includes steps of providing a biometric reading by a user (such as a card), receiving medical data from a database when the biometric reading positively correlates with a biometric reading associated with the medical data stored in the database and displaying the medical data only in response to the user's biometric reading whose medical records are being accessed (Column 8).

Regarding Claim 18 Beecham teach that when the biometric data submitted by the user does not match stored biometric data the data retrieval process is either terminated or the user is asked to enter new or revised biometric data (Column 18). This is being interpreted as a warning.

Regarding Claim 25 Beecham teach that when the biometric data submitted by the user does not match stored biometric data no stored medical information can be

released until the biometric data being entered by the user matches the biometric data stored in the database (column 18).

5. Claims 8 and 9 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Beecham (US Patent 5876926 Issued 1999) in view of Staub (US Patent 6187540 Issued 2001) and Wohlgemuth (US Patent 6905827 Filed 2002) as applied to claims 6, 7, 15, 18, and 25 above and in further view of Noblett et al (US Patent 6362004 Issued 2002).

The teachings of Beecham, Staub, and Wohlgemuth are presented above in paragraph 4.

The combined references do not teach that the DNA microarray has a first indicator which indicates the first DNA probe group and a second indicator which indicates the second DNA probe group.

However Noblett et al teach the use of fiducial marks on microarrays to precisely determine the location of each probe on the array. Noblett et al teach that microarrays may contain multiple fiducials which can be used for positioning. Additionally Noblett teaches that fiducials can be used to differentiate between arrays when there are multiple arrays on a microarray (Column 7).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Beecham et al so as to have used a DNA microarray comprising a set of fiducials in order to have achieved the

benefits of Noblett of using a method utilizes fiducial marks in order to determine the location of each probe on the array.

6. Claims 17 and 19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Beecham (US Patent 5876926 Issued 1999) in view of Staub (US Patent 6187540 Issued 2001) and Wohlgemuth (US Patent 6905827 Filed 2002) as applied to claims 6, 7, 15, 18, and 25 above and in further view of Honda et al (US Patent 6021393 Issued 2000).

The teachings of Beecham, Staub, and Wohlgemuth are presented above in paragraph 4.

The combined references do not teach a method comprising a recording step wherein the identification information and test results information are recorded on the patient's medical information card.

However Honda et al teaches the concept of portable memory cards carried by a patient to store the patient's personal medical information. The card can store the results from medical tests and various personal information. Then when the patient goes to the hospital or to see a doctor for the first time the patient can let the doctor know about his or her morbid state by only presenting the medial information card. (Abstract and Column 3).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Beecham et al so as to

have included a recording step wherein the identity information and the test results are recorded on a medical identification card that the patient can keep in order to have achieved the benefits of Honda of providing a medical information card that can store the patients medical data allowing his medical history to be readily available to treating physicians thereby cutting down on hospital mistakes made by doctors.

7. Claim 26 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Beecham (US Patent 5876926 Issued 1999) in view of Staub (US Patent 6187540 Issued 2001) and Wohlgemuth (US Patent 6905827 Filed 2002) as applied to claims 6, 7, 15, 18, and 25 above and in further view of Anderson (PG Pub 20010012537).

The teachings of Beecham, Staub, and Wohlgemuth are presented above in paragraph 4.

The combined references do not teach a method further comprising a step of identifying the microarray.

However Anderson et al teach that it is important to have identifiers on the microarrays. Anderson et al teach that the identifiers may be part of the array itself or the array may have a machine-readable indicia such as a barcode to provide identification and orientation.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Beecham et al so as to have used a microarray which has a barcode as suggested by Anderson for the benefit of being able to scan the barcode to determine the identity of the microarray.

RESPONSE TO ARGUMENTS

8. In the response filed January 19, 2007 Applicants have described their invention and the benefits of their invention. However the claims have been examined based on what they recite and the claim language is given the broadest reasonable interpretation. The applicant's main argument is that the combined references of Beecham, Staub, and Wohlgemuth et al fail to teach a step of comparing the first identification code or number acquired from a DNA microarray with a identification code stored in a data base. This argument has been fully considered but is not persuasive because the method of Beecham desirably includes a step of providing the test subject with a unique alphanumeric correlation code. Therefore in the method of Beecham there are three things which get stored as a single record in the database: the unique alphanumeric correlation code, the biometric indicia (gene sequences), and the test result. Therefore if one was interested in determining whether or not a test subject was new all they would need to do is search the database for the unique alphanumeric correlation code. It is also noted that in the applicant's response they have argued that the personal identification code is obtained from a hybridization pattern (Page 12). However the claims as written do not state this. For instance there are no active process steps by which an identification code is obtained from a hybridization pattern in the claims of the present invention.

Conclusion

9. No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw
Examiner.
Art Unit 1634

DIANA JOHANNSEN
PRIMARY EXAMINER